Exhibit 5

THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

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IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION	:	MDL NO. 2804
THIS DOCUMENT RELATES TO ALL CASES:	:	CASE NO. 1:17-MD-2804 Hon. Dan A. Polster

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Friday, April 26, 2019

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HIGHLY CONFIDENTIAL - SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

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Videotaped deposition of DAVID A. KESSLER, M.D. (Day 2), taken pursuant to notice, was held at Baron & Budd, 600 New Hampshire Avenue NW, Floor G, Washington, DC 20037, beginning at 8:07 a.m., on the above date, before Lisa V. Feissner, RDR, CRR, Notary Public.

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MR. RAFFERTY: Object to the form.
A. I would agree with that.
Q. Okay. You always have and continue to have every reason to trust the judgment of officials of the FDA; is that correct?
MR. RAFFERTY: Object to the form.
A. I wouldn't -- sitting here today, I wouldn't say it like that.
Q. Okay.
A. I said I have enormous respect for the people who work at the agency, but like any other organization that has 10,000 people, there are people whose judgment I would trust with my life, and there are -- like any organization, there are clunkers.
And so I would not make a blanket statement across the board. I have enormous respect.
Q. Janet Woodcock, the head of CDER, you would put her in the category of someone you have enormous respect for?
A. I appointed Janet.
Q. That's not the question I asked.
Do you have enormous respect for

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Janet Woodcock?
A. Respect? Sure. I appointed her. I picked her out. She was a, you know, three-level medical reviewer, and I made her the head of the center ten years ahead of when she was supposed to be. I have enormous respect.
Do I agree -- I have enormous respect for her contribution to service, to her integrity. Has she made mistakes? Absolutely. Do I disagree with her? Absolutely. Have we had conversations like that? Absolutely.
I defended Janet Woodcock, I mean, you know, pretty vigorously because I thought people at the agency should get defended in certain circumstances.
Q. What about Carl Peck? Would you say the same about him?
A. Carl Peck, you have to love. Carl Peck -- I would trust Carl Peck with pharmacokinetics because he sees pharmacokinetics in everything. And I think he contributed and we worked mightily together.
Do I agree with him on everything?

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Absolutely not. Do I think every question can be answered by a PK analysis? Absolutely not. Did he make a mistake on pilot drug, et cetera? We could spend hours talking. But I love Carl Peck, and enormous respect for Janet.
Q. The FDA has the highest safety and efficacy studies in the world, right?
A. Studies in the world, no. FDA doesn't do studies. The manufacturers does the studies. So I'm not sure what that -- the question means.
Q. The doctors and scientists at FDA are as smart and talented as any you've ever seen; is that right, sir?
MR. RAFFERTY: Object to the form.
A. That's exactly the kind of statement that I made earlier. If you're asking me, there are those who are very talented, and there are those who are clunkers, and there are those who could earn umpteen dollars times their salary on the outside and are pure gold, and there are others who make mistakes. And even those who you trust sometimes make mistakes. And we all do that.

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Q. Do you agree that the United States food and drug laws have the highest safety and efficacy standards in the world?
MR. RAFFERTY: Object to the form.
A. I did at a point in time.
Q. Do you agree now, as you sit here today?
A. I think in certain areas, we may be being usurped by certain of the European -- in certain areas. I think that was probably true at a point in time, but I have some concerns in certain areas.
Q. If a company gets a warning letter and the company wanted to be a model citizen, one thing it would do -- the first thing it would do is immediately stop using the offending promotional materials. That's one thing you would want to see a company that got a warning letter do, correct?
A. Sure. But I think there would be something you'd want to do first.
Q. Another thing you would want a company to do when it gets a warning letter from the FDA about promotional materials is to

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work with the FDA to formulate a corrective action plan, right?
A. Sure. But I would think there would be something even more important.
Q. What first? What would one want to do first?
A. You'd want to look and see not just what this promotional material was or what your corrective action plan, you would want to understand the corporate strategy or the corporate culture that contributed to that warning letter, and you would want to make sure you would change that corporate culture or that corporate strategy rather than just discarding X piece of paper or coming up with a plan. That's what I think it is more important when you got a warning letter.
Q. So if you're advising a company as to how to be a model citizen and do the right thing when you get a warning letter, you need to figure out why the statement got in and correct that as a matter of corporate conduct? Is that what you're saying?
A. Sure. But you'd have to ask

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yourself -- there's a term -- and I'm not a big fan of it, the term. It's a little bit of a slogan, but it's a culture of compliance. And is there anything in that culture of compliance that is off, that begat that warning letter.
Q. You'd also want to work with the FDA and create a corrective action plan that was effective, correct? Yes or no?
A. Sure, yes.
Q. And you are aware that Actavis got a warning letter with respect to Kadian. That's something that you talk about in your report, right?
A. 2010, I believe, yes.
Q. And, in fact, Actavis did immediately stop using the materials. You're aware of that?
A. I am.
Q. And Actavis also worked with the FDA to create a corrective action plan, correct?
A. Correct.
Q. And you are aware that the FDA agreed with and said it appreciated the

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corrective action plan, correct? Are you aware of that?
A. I'm not sure the word "appreciated," but I'll take your stipulation to that. I don't recall, but I'll -- I'm sure the FDA said something akin to that.
Q. And part of the corrective action plan was to send Dear Healthcare Professional letters to every physician who had received the projects materials.
Are you aware of that?
A. Correct.
Q. In addition, part of the corrective action plan was to send additional letters out to consumers, correct?
A. Correct.
Q. Okay. And you don't have any reason to believe that the FDA was dissatisfied with that corrective action plan, do you?
A. Correct.
Q. Okay. There was no enforcement action or any further action taken on Kadian by the FDA at any point in time after that, correct?

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A. Correct. And we see the decrease in numbers and eventually the decrease in promotion, et cetera, that followed shortly, and we see this inflection point in Kadian's sales.
Q. Do you believe that Actavis did the right thing when it got its warning letter?
A. I have no reason to doubt that.
Q. Okay. There's another document that you cited in your report in paragraph 520 that you take issue with for Actavis.
A. If I can find my report.
Q. Your report is buried in my pile, too. Let's look together.
A. 520?
Q. I think that's correct. Let me turn to it.
MS. LEVY: There's a request for a break. Let's go off the record.
THE WITNESS: I think 520 raises some questions.
MS. LEVY: Hang on a second. Let's go off the record.
VIDEO OPERATOR: 4:40 p.m., we're

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off the video record.
(Recess from 4:40 p.m. until 4:53 p.m.)
VIDEO OPERATOR: 4:53, we're on the video record.
BY MS. LEVY:
Q. Doctor, you once referred to the FDA processes as being the gold standard for drug approval.
Do you still have that opinion today?
A. I think so.
Q. How many opioids were approved in the Kessler administration?
A. I don't know -- I mean, the ones obvious -- there were approved -- let me just do it in my head. Duragesic was approved before me.
There were two. There was Kadian, and as far as brand name drugs, Kadian and Duragesic -- I'm sorry -- Kadian and Oxy were done during that seven-year period. I'd have to look and see how many on the generic side.
Q. Do you know the number of

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opioids -- just do you know the number of opioids that were approved during the Kessler administration?
A. I can tell you NDAs.
Q. How many? Number only.
A. I believe there were two NDAs.
Q. How many ANDAs?
A. I don't have that number.
Q. You don't know?
A. I don't know.
Q. The FDA continues to approve opioid products on an ongoing basis, correct? Let me -- I worded that poorly.
The FDA continues to approve new opioid products on an ongoing basis, continuing through today, right?
MR. RAFFERTY: Object to the form.
A. There's an issue with regard to that in my conversations with the Commissioner, but the way the statute is written, there's some discussion of whether that needs to be changed.
Q. Not my question.
The FDA continues to approve

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opioids, this year has even approved opioids, correct?
A. This year, it would be fair. But when you say "continued," you're implying into the future, and I'm just saying there is an issue about that.
Q. Okay. The FDA approved new opioids in 2015, '16, '17, '18 and '19, correct?
A. And some to great criticism.
Q. No doubt that the FDA has been criticized widely by some folks for doing so.
But it continues to approve these products, correct?
A. Including me.
MR. RAFFERTY: Object to the form.
Q. And there have been a number of citizens' petitions and other requests to the FDA to make changes and to make -- to take certain actions with respect to opioids on the market.
You're aware of those, right?
MR. RAFFERTY: Objection.
A. We've discussed those in the past two days.

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Q. And you disagree with the FDA's opinions and outcomes in responding to those petitions? You disagree with the FDA in that, right?
MR. RAFFERTY: Object to the form.
A. I don't think that's a fair statement. That's not my testimony. If you want to show me a specific sentence in FDA, I can tell you what I would agree with and what I disagree. I won't make a blanket statement --
Q. That's fair.
A. -- that I agree or I disagree.
Q. And I believe we established this earlier in the record, but just in case.
You are not giving testimony or speaking for the FDA, correct?
A. That's correct.
Q. You haven't been employed by the food -- by the Health and Human Services Department since the -- 21 years; is that right?
A. You can do the math at this hour. But I would certainly -- it's very important, underscore it, put an asterisk, put an

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exclamation point. I'm in no official capacity. Sometimes I get put on television because they're not -- sometimes I get put on television because the agency is not speaking. But I have no official capacity.

Q. Okay. There are plenty of things that you disagree with the FDA on, right?

A. Things I agree with them and things I disagree with them.

Q. Okay. Now, the -- one of the things you believe is that Kadian should not be prescribed for chronic pain, right? Or is that an overstatement?

A. So I think if you did that, if you just left it that way, I think that would be inaccurate.

Q. Okay. Do you have any -- strike that.

Kadian was approved by the FDA in 1996 for use in patients with chronic moderate to severe pain who require repeated dosing with a potent opioid analgesic, correct?

A. I thought it said continuous, around-the-clock. Do you want to just give

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me -- maybe I'm misreading.

Q. Let me -- let me read you --

A. Just give me the indication. I can pull it. Let me pull it.

Q. I just want to ask -- I'm asking -- we're going to do that in a minute, but listen to this specific question, and I would like to know if you agree or disagree.

A. Okay. I'm just pulling the label so I can be exact. But go ahead. I'm listening, ma'am. I don't want to delay.

Q. No. Take your time. Do what you need to do. Put the label in front of you.

And for the record, are you looking at your report?

A. Just looking at the schedules that have the labels, and I'm looking specifically for Kadian and multiple changes, and let's just look at the indications section -- I'm just trying to get the indications section -- interactions with alcohol -- go ahead. Just read me the indications section, or read me whatever you want.

Q. So no, that's not my question,

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actually. I want to wait until you can pay attention to the question I'm going to ask you.

A. Sure. And I apologize. I'm just trying to pull the labeling.

Q. Would you like to see the Kadian current label?

A. I'd love to see it in 1996. That's what I -- and I apologize --

Q. I'm going to give you just another minute, and then I'm going to move on with my question.

A. Keep going on, please.

Q. Okay. I'm going to say a statement, and I want to know if you agree. And here is the statement: Kadian was approved by the FDA in 1996 for use in patients with chronic moderate to severe pain who require repeated dosing with a potent opioid analgesic.

That's true, right?

A. No, I'd want to see the label before I'd answer that question.

(Exhibit Kessler-45 marked for identification and attached to the transcript.)

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BY MS. LEVY:

Q. Let's mark -- let me hand you what I've marked as Kessler Exhibit 45.

A. Thank you very much, ma'am.

Q. Okay. And this is a document dated July 11th, 1997. You see in the top right-hand corner?

THE WITNESS: Can I ask someone just get me the Kadian label, the approved label, please? Yeah, thank you.

A. I see this.

Q. Okay. And you recognize the letterhead on this document as FDA Center For Drug Evaluation and Research. You recognize that letterhead?

A. I know that letterhead.

Q. And the Center For Drug Evaluation and Research is often referred to as CDER, right?

A. Correct.

Q. CDER's understanding on July 11th, 1997 was that Kadian was approved by the FDA in 1996 for use in patients with chronic, moderate